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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,291	03/01/2004	G. Barrie Kitto	CLFR:232US	9495

7590 02/10/2006

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,291	KITTO ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 3-6, drawn to a plant that expresses a sperm-specific polypeptide from murine lactate dehydrogenase-C, classified in class 800 , subclass 288, for example.
- II. Claims 1, 3-4, and 6, drawn to a plant that expresses a sperm-specific polypeptide from rat lactate dehydrogenase-C, classified in class 800, subclass 278, for example.
- III. Claims 7-8 and 14-15, drawn to a method comprising providing to an animal a plant expressing a sperm-specific polypeptide, classified in class 426, subclass 2, for example.
- IV. Claims 1 and 6, drawn to a plant that expresses an egg-specific polypeptide, classified in class 435, subclass 468, for example.
- V. Claims 7-8, drawn to a method comprising providing to an animal a plant expressing an egg-specific polypeptide, classified in class 426, subclass 1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related to invention III as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the plants of invention I and II could be used for a different method, for instance, the polypeptide could be purified out of the plants and added to a composition. In addition, the method of invention III could be practiced with a different material, for instance lactate dehydrogenase could be added to an animal feed and then the mixture can be fed to the animals.

A search for the inventions of groups I and II will require searching the literature for nucleic acids encoding lactate dehydrogenase-C and a search for transgenic plants heterologously expressing polypeptides. A search for the method of group III will require searching for methods of decreasing fertility of an animal and methods of baiting animals. Because these searches are not coextensive, it would constitute an undue burden to examine the inventions together.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the plants of invention IV could be used for a different method, for instance, the polypeptide could be purified out of the plants and added to a

composition. In addition, the method of invention V could be practiced with a different material, for instance an egg-specific polypeptide could be added to an animal feed and then the mixture can be fed to the animals.

A search for the invention of group IV will require searching the literature for nucleic acids encoding egg-specific polypeptides and a search for transgenic plants heterologously expressing polypeptides. A search for the method of group V will require searching for methods of decreasing fertility of an animal and methods of baiting animals. Because these searches are not coextensive, it would constitute an undue burden to examine the inventions together.

The inventions of groups I-III are patentably distinct from the inventions of groups IV-V. The inventions of groups I-III utilize a different polypeptide than the inventions of group IV-V, therefore the plants of groups I-II are not the same plants as the plants of group IV. The methods of groups III and V do not utilize the same materials, therefore they are patentably distinct methods.

A search for the inventions of groups I-III will require searching the literature for nucleic acids encoding lactate dehydrogenase-C and a search for transgenic plants heterologously expressing polypeptides as well as a search for how lactate dehydrogenase-C influences fertility in animals. A search for the invention of group IV will require searching the literature for nucleic acids encoding egg-specific polypeptides and a search for transgenic plants heterologously expressing polypeptides as well as a search for how egg-specific polypeptides

influence fertility in animals. These searches are not coextensive, it would constitute an undue burden to examine the inventions together.

The inventions of groups I and II are patentably distinct. The invention of group I utilizes murine lactate dehydrogenase-C whereas the invention of group II utilizes rat lactate dehydrogenase-C. These are different proteins encoded by different nucleic acids, and therefore they are patentably distinct molecules.

A search for the invention of group I will require searching the databases and literature for nucleic acids encoding a murine lactate dehydrogenase-C. A search for the invention of group II will require searching the databases and literature for nucleic acids encoding a rat lactate dehydrogenase-C. These searches are not coextensive, and therefore it would constitute an undue burden to examine the inventions together.

Claim 2 links the inventions of group I and group II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 2. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional

application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant applications. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

The examiner has required restriction between product (groups I and II) and process (group III) claims; in addition a restriction between another product (group IV) and process (group V). Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability

including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
Feb. 2, 2006

Cynthia Collins 2/6/06
CYNTHIA COLLINS
PRIMARY EXAMINER
ART UNIT 1638